DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

APR 23 2001

WARNING LETTER

RETURN RECEIPT REQUESTED
CERTIFIED MAIL

Director/CEO
R&G Medical and Development Corporation
10664 Avenida Santa Ana
Boca Raton, Florida 33498

Dear Sir/Madam:

We are writing you because the Food and Drug Administration (FDA) obtained information about your Self Pap device which you exhibited at the International Consensus Conference on March 18, 2000. This product is considered to be a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act, manufacturers of medical devices are required to obtain marketing clearance for their products from the FDA before they may offer them for sale in this country.

At the conference, you claimed that your device did not have to be cleared/approved by the FDA since it is a Class I, general controls device under 21 CFR §878.1800. Promotional materials indicate that the Self Pap device is to be used by any woman. Its purpose is the collection of endocervical cells for pap smear analysis to be performed by a designated clinical laboratory for the purpose of cervical cancer screening. This intended use is outside the scope of the 21 CFR §878.1800.

Our records do not show that you obtained marketing clearance before you began offering your product for sale in this country. Because you do not have marketing clearance from FDA, marketing your product in this country is a violation of the Act. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not submit information that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed in this country.

You can obtain FDA's requirements on the type of information to be included in a premarket notification for this device by contacting Mr. Collin M Pollard, Chief of the Obstetrics/Gynecology Devices Branch, at 301-594-1180. Please note that a guidance document outlining data and labeling requirements for this device can be found at http://www.fda.gov/cdrh/ode/odec1272.html.

You should know that these serious violations of the law may result in FDA taking regulatory action without any further notice to you. These actions include, but are not limited to, seizing your product inventory in this country, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

Also, you may be subject to Section 5 of the Federal Trade Commission Act (15 U.S.C.§45), which prohibits deceptive acts or practices in or affecting commerce. Also, Section 12 of the Federal Trade Commission Act (15 U.S.C.§52) prohibits the dissemination of any false advertisement to induce the purchase of any food, drugs, or devices.

It is necessary for you to take action on this matter now. Please let this office know, in writing, within fifteen(15) working days from the date that you receive this letter what steps you are taking to correct the problem involving the sale of a unapproved/uncleared products by your company. We also ask that you explain how you plan to prevent this from happening again and what you will do about unapproved/uncleared products currently in retail outlets. If you need more time, please let us know why and when you expect to complete your correction. Please direct your response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, Center for Devices and Radiological Health, 2094 Gaither Road, HFZ-321, Rockville, MD 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture, and marketing of medical devices. This letter pertains only to the issue of premarket clearance or approval for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting

our Division of Small Manufacturers Assistance at 1-800-638-2041 or on the Internet at http://www.fda.gov/cdrh/devadvice/11.html.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of the letter, please feel free to contact Augustin Gonzalez-Licea, MD. at (301) 594-4595 ext.171.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Revised 04/24/01

Prep: AGonzalez-Licea: 09/23/00
Revised: BStaples:11/15/00
Revised: CPollard:11/08/00
Revised: CReynolds:10/18/00
Final:jap 11/17/00
Revised:Agonzalez 2/21/01; 3/28/01
Final:jap 2/22/01; 3/28/01; 4/18/01
Revised: JRKirk 4/19/01
Final: dr 4/20/01

JRK 4/20/01

4/20/01

Cc:
HFZ-300
HFA-224
HFZ-230
HFC-320 (3)
HFZ-321
HFZ-470
HFR-PA200
HFR-PA240 (Sawyer)
HFI-35 (purged)
HFZ-306 (2, 1 purged for L. Silver and 1 for Branch)

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